

new claim 7 as outlined in Appendix A, attached herewith.

REMARKS

Applicants take this opportunity to thank Examiners Woodward and Sasan for the in-person interview conducted with applicants' representative on November 14, 2007.

Upon entry of the above amendment, claims 1 and 3-7 will be pending in the present application. Applicants respectfully submit that neither the claim amendments nor the new claim add any new matter within the meaning of 35 USC §132.

1. Rejection of claims 1-6 under 35 U.S.C. §103(a)

The Official Action states that claims 1-6 are rejected under 35 U.S.C. §103(a) as being unpatentable over Higo et al. (U.S. Patent No. 5,866,157) in view of Arth et al. (U.S. Patent No. 6,461,636).

RESPONSE

Applicant respectfully traverses this rejection of claims 1-6. The cited references do not establish a *prima facie* case of obviousness against the presently pending claims. To establish a *prima facie* case of obviousness, the PTO must satisfy three requirements. First, as the U.S. Supreme Court recently held in KSR International Co. v. Teleflex Inc. et al., Slip Opinion No. 04-1350, 550 U.S. (April 30, 2007), "a

court must ask whether the improvement is more than the predictable use of prior art elements according to their established functions. ...it [may] be necessary for a court to look to interrelated teachings of multiple patents; the effects of demands known to the design community or present in the marketplace; and the background knowledge possessed by a person having ordinary skill in the art, all in order to determine whether there was an apparent reason to combine the known elements in the fashion claimed by the patent at issue. ...it can be important to identify a reason that would have prompted a person of ordinary skill in the relevant field to combine the elements in the way the claimed new invention does... because inventions in most, if not all, instances rely upon building blocks long since uncovered, and claimed discoveries almost of necessity will be combinations of what, in some sense, is already known." (KSR, supra, slip opinion at 13-15). Second, the proposed modification of the prior art must have had a reasonable expectation of success, determined from the vantage point of the skilled artisan at the time the invention was made. Amgen Inc. v. Chugai Pharm. Co., 18 USPQ 1016, 1023 (C.C.P.A 1970). Lastly, the prior art references must teach or suggest

all the limitations of the claims. In re Wilson, 165 USPQ 494, 496 (C.C.P.A. 1970).

Further, the Supreme Court in KSR reiterated the framework for determining obviousness that was stated in Graham v. John Deere Co. 383 U.S. 1, 148 USPQ 459 (1966). The four factual inquiries that were recited in Graham are as follows: (1) Determining the scope and contents of the prior art; (2) Ascertaining the differences between the prior art and the claims in issue; (3) Resolving the level of ordinary skill in the pertinent art; and (4) Evaluating evidence of secondary considerations, such as unexpected results. Id. As stated in **MPEP 2141**, secondary considerations such as unexpected results must be considered in every case in which they are present.

A. The Presently Claimed Invention

The presently claimed invention as exemplified by currently amended independent claim 1 is directed to:

A patch comprising a backing layer and an adhesive layer disposed on the backing layer and compounded with a drug and an adhesive base agent, wherein the adhesive base agent comprises styrene-isoprene-styrene block copolymer, 2-ethylhexyl acrylate - vinyl acetate copolymer and a basic nitrogen-including polymer including a basic nitrogen and having no adhesion property at normal temperature selected from the group consisting of methyl methacrylate - butyl methacrylate - dimethylaminoethyl methacrylate terpolymer and polyvinyl acetal diethylamino acetate.

B. The Teachings of the Higo et al. Reference

The Higo et al. reference teaches a matrix type patch formulation comprising an adhesive layer containing a physiologically active substance, an organic acid, a hydrophobic high molecular material, a tackifying resin, a plasticizer and an absorption enhancer. Higo et al. does not explicitly teach the use of the drug pergolide as a component of the adhesive layer of the patch formulation, and discloses the general use of drugs in the adhesive layer to treat Parkinson's disease. Further, Higo et al. does not disclose the adhesive layer containing a "styrene-isoprene-styrene block copolymer, 2-ethylhexyl acrylate-vinyl acetate copolymer and a basic nitrogen-including polymer including a basic nitrogen and having no adhesion property at normal temperature" of the presently pending claims.

C. The Teachings of the Arth et al. Reference

The Arth et al. reference teaches a transdermal therapeutic system for the delivery of pergolide. Arth et al. does not disclose the adhesive layer containing a "styrene-isoprene-styrene block copolymer, 2-ethylhexyl acrylate-vinyl acetate copolymer and a basic nitrogen-including polymer including a

basic nitrogen and having no adhesion property at normal temperature" of the presently pending claims.

**D. No *prima facie* Case of Obviousness has Been Shown by the
Examiner**

There is no teaching in the cited references which would motivate the skilled artisan to combine the matrix patch formulation of the Higo et al. reference with the transdermal therapeutic system of the Arth et al. reference to achieve the results obtained using the transdermal patch formulation recited in the presently pending claims. Without such a teaching, the skilled artisan would have absolutely no motivation to take the teachings of these references to arrive at the presently pending claims.

As such, the Examiner has provided no reason to combine the known elements in the fashion claimed by the applicants. Accordingly, the Examiner has failed to establish a *prima facie* case of obviousness.

E. The Unexpectedly Superior Properties of the Claimed Matrix

As stated in MPEP 716.02, the rationale to support a conclusion that the claims would have been obvious is that all

the claimed elements were known in the prior art and one skilled in the art could have combined the elements as claimed by known methods with no change in their respective functions, and the combination would have yielded nothing more than predictable results to one of ordinary skill in the art at the time of the invention. Accordingly, Applicants' data submitted in the present specification shows unexpected, and thus unpredictable results for the formulations comprising the claimed components.

As discussed during the interview of November 14, 2007, the applicants kindly bring the Examiner's attention to the unexpectedly superior properties of the claimed matrix outlined in Tables 1-4 on pages 34-39 of the instant specification. The data clearly shows enhanced maximum skin permeation rates for the drug pergolide in those examples that contain all three components as recited in the presently pending claims when compared to the examples where one or more of the claimed components are not present in the composition. Examples 1-3 summarized in Tables 1 and 2 show drug permeation rates per unit area of skin for compositions containing the presently claimed components. Comparative Examples 1-10 in Tables 1 and 2 show drug permeation rates for compositions lacking at least one of

the components of the claimed formulation. The data clearly shows superior skin permeation rates and patch properties, when compared to the drug permeation rates for compositions lacking at least one of the claimed components.

Similarly, the results for Examples 4-7 outlined in Tables 3 and 4 shows unexpectedly superior skin permeation rates for compositions consisting of the claimed components and using the drugs Nifedipine, Nitrendipine, and Indomethacin, as compared to Comparative Examples 11-22, which also contained the aforementioned drugs, but lacked at least one of the components of the claimed formulation.

Accordingly, the results outlined in Tables 1-4 on pages 34-39 of the instant specification shows unexpectedly superior results for the compositions consisting of the claimed components. As such, the presently pending claims are not obvious over the cited prior art references. Accordingly, applicants respectfully request that the Examiner reconsider and withdraw the rejection of claims 1, and 3-6.

2. Provisional Rejection of Claims 1-2 and 4-6 under the Judicially Created Doctrine of Obviousness-Type Double Patenting

The Official Action states that claims 1-2 and 4-5 are provisionally rejected under the judicially created doctrine of

obviousness-type double patenting as being unpatentable over claims 1-11 of copending U.S. Patent Application Serial No. 10/526,065.

Applicants respectfully request that the Examiner hold this rejection in abeyance until such time as the Examiner indicates there is successful resolution of the claim rejections noted above. At that time, pursuant to MPEP Section 804 (B)(1), Applicants respectfully submit that the nonstatutory obviousness-type double patenting rejection will be the only rejection remaining in the instant application. Because both applications in question were filed on the same day, and the copending application has not yet been examined, it is proper for the Examiner to withdraw this rejection in the instant application and permit the application to issue as a patent without a terminal disclaimer, and this rejection should be made in application Serial No. 10/526,065.

CONCLUSION

Based upon the above remarks and amendment, the presently claimed subject matter is believed to be novel and patentably distinguishable over the prior art of record. The Examiner is therefore respectfully requested to reconsider and withdraw all rejections and allow all pending claims in this application.

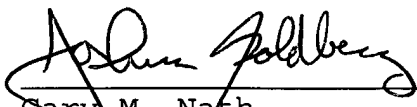
Favorable action with an early allowance of the claims pending in this application is earnestly solicited.

The Examiner is welcomed to telephone the undersigned attorney if she has any questions or comments.

Respectfully submitted,
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